

1012 ANTIMICROBIAL - chloroxylenol soap
ABC Compounding Co., Inc.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

1012 Antimicrobial 6544 Drug Facts and Label

Drug Facts Box OTC-Active Ingredient Section

Chloroxylenol 0.3%

Drug Facts Box OTC-Purpose Section

Antiseptic

Drug Facts Box OTC-Indications & Usage Section

for hand-washing to decrease bacteria on the skin

Drug Facts Box OTC-Warnings Section

for external use only

Drug Facts Box OTC-When Using Section

do not get into eyes

if contact occurs, rinse eyes thoroughly with water

Drug Facts Box OTC-Stop Use Section

irritation and redness develop

Drug Facts Box OTC-Keep Out of Reach of Children Section

if swallowed, get medical help or contact a Poison Control Center right away

Drug Facts Box OTC-Dosage & Administration Section

wet hands and forearms

apply 5 milliliters (teaspoonful) or palmful to hands and forearms

scrub thoroughly for 1 minute and rinse

Drug Facts Box OTC-Inactive Ingredient Section

water, decyl glucoside, sodium laureth sulfate, cocamide MIPA, propylene glycol, sodium chloride, citric acid, DMD hydantoin, fragrance, FD and C yellow no.5, food red 10

1012 Antimicrobial 6544 1 gallon bottle

**KEEP OUT OF REACH OF CHILDREN
AN INSTITUTIONAL PRODUCT
NOT FOR HOUSEHOLD USE**

SPURRIER



This product is an effective antibacterial hand soap for use in food processing plants and restaurants by personnel prior to handling food and/or food processing equipment.

This formulation effectively reduces the bacterial flora of the skin. When tested via the Time Kill Test, it demonstrates 99% or greater kill against *Staphylococcus aureus*, *E. Coli*, and *Pseudomonas aeruginosa*. Formulated with skin conditioners for extra mildness.

This product is designed exclusively for industrial and institutional use by trained personnel. This product is sold as is and the manufacturer makes no warranty, express or implied, of merchantability, fitness for a particular purpose or otherwise.

1012 ANTIMICROBIAL HAND SOAP

CAUTION

KEEP OUT OF REACH OF CHILDREN

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle.
(If you do not understand this label, find someone to explain it to you in detail.)

NET CONTENTS: 1 Gallon (3.8 L)

Manufactured by:
ABC Compounding Co., Inc.
P. O. Box 16247, Atlanta, GA 30321-0247

Drug Facts	
Active Ingredient	Purpose
Chloroxylenol 0.3%	Antibiotic
Uses For hand washing to decrease bacteria on the skin.	
Warnings	
For external use only	
When using this product	
<ul style="list-style-type: none"> ■ do not get into eyes ■ If contact occurs, rinse eyes thoroughly with water 	
Stop use and ask a doctor if	
<ul style="list-style-type: none"> ■ irritation and redness develop. 	
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	
Directions ■ wet hands and forearms	
<ul style="list-style-type: none"> ■ apply 5 milliliters (teaspoonful) or palmful to hands and forearms ■ scrub thoroughly for 1 minute and rinse 	
Inactive Ingredients water, decyl glucoside, sodium lauryl sulfate, cocamide MEA, propylene glycol, DEXM hydration, sodium citrate, citric acid, fragrance, FD&C yellow no. 5, food red 10.	



65442PSP-65444PSP1219B

Batch No.: XXXX

1012 Antimicrobial 1 gallon bottle

1012 ANTIMICROBIAL

chloroxylenol soap

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62257-012
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CHLOROXYLENOL (UNII: 0F32U78V2Q) (CHLOROXYLENOL - UNII:0F32U78V2Q)	CHLOROXYLENOL	3 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
DECYL GLUCOSIDE (UNII: Z17H97EA6Y)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
COCO MONOISOPROPANOLAMIDE (UNII: 21X4Y0VTB1)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62257-012-06	1 in 1 BOX	05/01/2013	
1		800 mL in 1 BAG; Type 0: Not a Combination Product		

2	NDC:62257-012-17	532 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/01/2013	
3	NDC:62257-012-10	1000 mL in 1 CARTRIDGE; Type 0: Not a Combination Product	05/01/2013	
4	NDC:62257-012-11	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/01/2013	
5	NDC:62257-012-14	3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/01/2013	
6	NDC:62257-012-55	208200 mL in 1 DRUM; Type 0: Not a Combination Product	05/01/2013	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	05/01/2013	

Labeler - ABC Compounding Co., Inc. (003284353)

Establishment

Name	Address	ID/FEI	Business Operations
ABC Compounding Co., Inc.		003284353	manufacture(62257-012)

Revised: 12/2018

ABC Compounding Co., Inc.